

Claims

1. (Currently amended) An oral dosage composition of a high molecular weight, lipophilic, bioactive agent, ~~comprising~~consisting essentially of:

a biologically effective amount of the bioactive agent;

a lipid matrix in which the bioactive agent is suspended; and

a sufficient amount of a polyphenol to improve gastrointestinal absorption of the bioactive agent when the dosage form is orally administered.
2. (Original) The composition of claim 1, wherein the lipid matrix comprises a triglyceride matrix that is a liquid at body temperature.
3. (Original) The composition of claim 2, wherein the triglyceride matrix comprises a soybean lipid matrix.
4. (Original) The composition of claim 1, wherein the bioactive agent has a molecular weight of at least 200.
5. (Original) The composition of claim 4, wherein the bioactive agent comprises one or more of a steroid; a steroid antagonist; a non-steroidal anti-inflammatory agent; an anti-hypertensive agent; an antioxidant; an anti-epileptic agent; an antibiotic; an antiviral agent; an anticancer agent; a neuroprotective agent; an anti-depressive agent; an enzyme; a coenzyme; a protein; a globulin; a vitamin; a retinoid; an immunological agent; a nucleotide; a lectin; or a growth factor.
6. (Currently amended) The composition of claim 3, wherein the triglyceride lipid matrix comprises a mixture of refined soybean oil; mono-, di- and triglycerides, and polyglycerol oleate and/or polyglycerol dioleate.

7. (Original) The composition of claim 6, wherein the di- and triglycerides are glycerides having side chains with 16 to 18 carbons.

8. (Previously presented) The composition of claim 1 wherein the polyphenol comprises one or more of:

- l) resveratrol;
- m) *Polygonum cuspidatum* extract;
- n) green tea extract;
- o) grape extract;
- p) grape seed extract;
- q) blackberry extract;
- r) blueberry extract;
- s) cranberry extract;
- t) elderberry extract;
- u) black current extract; or
- v) oolong tea extract.

9. (Withdrawn) The composition of claim 1 wherein the polyphenol or mixture of polyphenols comprises one or more of a di- and/or trihydroxyphenyl compound chosen from:

- a) catechins and substituted catechins;
- b) flavanols;

- c) flavondiols;
- d) theaflavins;
- e) thearubigens;
- f) anthocyanidin and substituted anthocyanidins;
- g) rutin and substituted rutin;
- h) tannins; or
- i) genistein and substituted genisten.

10. (Withdrawn) The composition of claim 9, wherein the polyphenol comprises a catechin and/or substituted catechin.

11. (Withdrawn) The composition of claim 10, wherein the catechin and/or substituted catechin comprises one or more of epicatechin, epicatechin gallate (ECG), epigallocatechin (EGC), epigallocatechin gallate (EGCG), or gallocatechin.

12. (Withdrawn) The composition of claim 9, wherein the polyphenol comprises one or more flavonols.

13. (Withdrawn) The composition of claim 12, wherein the flavonol comprises one or more of quercetin, kampferol, or myricetin.

14. (Original) The composition of claim 1, wherein the bioactive agent comprises a Coenzyme Q in either its reduced form (ubiquinone) or oxidized form (ubiquinol).

15. (Withdrawn) The composition of claim 8, wherein the polyphenol comprises *Polygonum cuspidatum* extract.

16. (Original) The composition of claim 8, wherein the polyphenol comprises resveratrol.
17. (Original) The composition of claim 1, further comprising an anti-oxidant other than the polyphenol or bioactive agent.
18. (Currently amended) The composition of claim 17, wherein the anti-oxidant comprises one or more of Vitamin A, Vitamin E (tocopherol), Vitamin K, Copper, Zinc, Iron, Selenium, beta-carotene, eriodictyol, carnosic acid, carnosol, ~~rosmarinic~~ rosmarinic acid, caffeic acid, coumaric acid, cinnamic acid, Coenzyme Q, Probucol, astaxanthin, lycopene, alpha-lipoate, and urate.
19. (Withdrawn) The composition of claim 1, wherein the bioactive agent comprises Coenzyme Q10, the polyphenol comprises *Polygonum cuspidatum* extract, and the lipid matrix comprises a mixture of refined soybean oil; mono-, di- and triglycerides, and polyglycerol oleate and/or polyglycerol dioleate.
20. (Withdrawn) The composition of claim 19, further comprising an anti-oxidant other than the Coenzyme Q10 or the polyphenol.
21. (Withdrawn) The composition of claim 20, wherein the anti-oxidant comprises tocopherol.
22. (Currently amended) The composition of claim 1, comprising, by weight, about 8-10% bioactive agent, less than about 1% polyphenol, and about 85-90% lipid matrix.
23. (Original) The composition of claim 1, further comprising 2-3% of an anti-oxidant other than the bioactive agent and polyphenol.

24. (Withdrawn) A method of improving absorption of a high molecular weight, lipophilic, bioactive agent in the gastrointestinal tract, the method comprising orally administering to a subject the composition of claim 1.

25. (Withdrawn) The method of claim 24, comprising administering the composition of claim 2.

26. (Withdrawn) The method of claim 25, comprising administering the composition of claim 3.

27. (Withdrawn) The method of claim 26, comprising administering the composition of claim 4.

28. (Withdrawn) The method of claim 27, comprising administering the composition of claim 5.

29. (Withdrawn) The method of claim 28, comprising administering the composition of claim 6.

30. (Withdrawn) The method of claim 29, comprising administering the composition of claim 17.

31. (Withdrawn) The method of claim 24, comprising administering the composition of claim 19.

32. (Original) The composition of claim 18, wherein the anti-oxidant comprises a pharmaceutically acceptable salt or ester of the anti-oxidant.

33. (Withdrawn) The composition of claim 21, wherein the tocopherol comprises a pharmaceutically acceptable ester of tocopherol.

34. (New) The composition of claim 1, consisting of:

the biologically effective amount of the bioactive agent;

the lipid matrix in which the bioactive agent is suspended; and

the sufficient amount of the polyphenol to improve gastrointestinal absorption of the bioactive agent when the dosage form is orally administered.

35. (New) An oral dosage composition of a high molecular weight, lipophilic, bioactive agent, comprising:

a biologically effective amount of the bioactive agent;

a lipid matrix in which the bioactive agent is suspended; and

a sufficient amount of a polyphenol to improve gastrointestinal absorption of the bioactive agent when the dosage form is orally administered, wherein the composition does not include a surfactant.